



Bureau of Radiological Health Mammography Program

INFORMATION NOTICE 09-01 01/16/2009

The following information is intended to inform facilities and staff of important changes and reminders regarding mammography regulations. Please review these items within your facility to ensure continued compliance with both State of Iowa and MQSA regulations.

- ◆ **Link to Mammography rules:** The mammography and stereotactic rules have been updated. The action limits for the stereotactic biopsy quality control tests have been clarified. Please review the changes to the rules for mammography – <http://www.legis.state.ia.us/aspx/ACODocs/DOCS/1-14-2009.641.41.6.pdf> and stereotactic biopsy – <http://www.legis.state.ia.us/aspx/ACODocs/DOCS/1-14-2009.641.41.7.pdf>
- ◆ **Installing new units:** There is a check list regarding the approval process for a new unit on our web site. It is located at <http://www.idph.state.ia.us/eh/mammography.asp>
- ◆ **Re-Accreditation:** When your facility goes through re-accreditation, it is no longer necessary to submit documents for continuing education or experience for the technologists and radiologists. We will send an attestation form with each re-accreditation. This will need to be signed by the lead radiologist. Actual documents will be reviewed on your facility's annual inspection.
- ◆ **40 hour Training Courses:** Please be sure that your currently approved in-house 40 hour training course reflects the current modality you are using. If you have switched to Digital or CR mammography you need to update your program to reflect that.

- ◆ **Trainer/Continuing Education changes:** Trainee and Trainer continuing education for direct supervision of patients will no longer be issued. This change is to align Iowa Department of Public Health with the ARRT CE Requirements. ARRT does not accept CE obtained through the performance of patient exams.
- ◆ **COMING SOON:** The IDPH Mammography website is under going changes. It will have an updated look, easier navigation, frequently asked questions (FAQ), applications, links to regulations, stereotactic section, information notices, and more!
- ◆ **IDPH Staff Updates:** In January 2008, Paul Koehn retired from the Bureau of Radiological Health.

For further information visit:

FDA website:

<http://www.fda.gov/cdrh/mammography>

FDA Policy Guidance Help System*:

<http://www.fda.gov/CDRH/MAMMOGRAPHY/robohelp/START.HTM>

IDPH – Mammography website:

<http://www.idph.state.ia.us/eh/mammography.asp>

Questions call:

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* The Policy Guidance Help System is a very helpful tool for finding official FDA answers to questions about the MQSA regulations. Before using the guidance, please check the State of Iowa rules to ensure that there is not a State regulation that is more stringent.